Smallpox Pre-Vaccination Information Packet: Contents and Instructions

The following information is for state and hospital personnel implementing smallpox vaccination programs.

Contents

1. **Cover Letter** – A letter from Dr. Julie Louise Gerberding, M.D., MPH., Director of the Centers for Disease Control and Prevention (CDC) to potential vaccinees explaining the purpose of the national smallpox preparedness program, encouraging individuals to know their health status and to err on the side of caution in making their vaccination decision and detailing the contents of the Smallpox Pre-Vaccination Information Package.
2. **Smallpox Vaccine Information Statement (VIS)** – This document, entitled "Smallpox Vaccine: What You Need to Know," contains basic information about smallpox disease, the benefits and risks of smallpox vaccine, who should not get the vaccine, what to do if a reaction occurs after vaccination, and where to get more information. The supplemental fact sheets listed below provide additional information.
    a. **VIS Supplement A: Reactions After Smallpox Vaccination** – informs readers about expected normal reactions following vaccination, as well as serious and life-threatening reactions.
    b. **VIS Supplement B: Vaccination Site Appearance and Care** – informs readers about the appearance and progression of a successful vaccination and the steps necessary to properly care for the vaccination site.
    c. **VIS Supplement C: Skin Conditions that Mean You Should Not Get Smallpox Vaccine** – informs readers about skin conditions that make a person more likely to experience rare and serious reactions.
    d. **VIS Supplement D: A Weakened Immune System Means that You Should Not Get Smallpox Vaccine** – informs readers about immune system problems that make a person more likely to experience rare and serious reactions.
    e. **VIS Supplement E: Pregnancy Means You Should Not Get the Smallpox Vaccine** – informs readers about the risks of vaccination during pregnancy and the risks of breastfeeding after vaccination.
3. **Pre-Event Screening Worksheet for Smallpox Vaccine** – a worksheet with questions to help individuals determine whether or not they should receive smallpox vaccine because of certain medical conditions that would place them at a greater risk for an adverse reaction from the vaccine. Some of these questions are of a personal and sensitive nature. Those implementing smallpox vaccination clinics should discuss, but not collect, this sheet.
4. **Someone You are Close to May Get Smallpox Vaccine: What You Should Know and Do** – a fact sheet that informs close contacts of people considering vaccination about the health conditions that put people at risk if they are in close physical contact with someone who has been vaccinated. This sheet also provides information about the steps close contacts can take to protect themselves.
5. **Fact Sheet: Investigational Vaccinia Immune Globulin (VIG) Information** – Vaccinia Immune Globulin (VIG) is an investigational new drug that may help people who have certain serious reactions to the smallpox vaccine. This sheet contains basic information about VIG, including possible side effects.

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6. **Fact Sheet: Investigational Vistide® (Cidofovir) Information** – Vistide (cidofovir), is a drug licensed to treat serious eye infections in HIV-infected people. The drug may help people who have certain serious reactions to the smallpox vaccine, but it has not been licensed for this purpose. This sheet contains basic information about cidofovir, including possible side effects.
7. **Smallpox Vaccine: Decision Point for the Smallpox Vaccine Candidate** – an 11-minute video intended as an overview for use at vaccination clinic sites to supplement the written materials listed above.
8. **Patient Medical History and Consent Form** – a form for clinic personnel to record patient information. The form also confirms the absence of contraindications and contains a consent signature line for the patients. This document **must be retained by the clinic** for 5 years or the length of time required by state law, whichever is longer.
9. **Post-Vaccination and Follow-Up Information Sheet** – This form serves as temporary proof of vaccination, contains follow-up appointment information, and instructs vaccine recipients on what to do if they think they are having an adverse reaction to the vaccine.

Instruction for Use

This package of materials is to be used as part of the national smallpox preparedness program to help ensure that potential vaccinees are adequately informed of the benefits and risks of smallpox vaccination, to assist in screening out individuals who should not receive the vaccine, and to obtain signed consent from those individuals who receive smallpox vaccine. In particular circumstances, the federal government will assume liability for injury or death attributable to a smallpox vaccination. The materials contained in this packet fulfill federal obligations to inform vaccinees about the risks and benefits of the smallpox vaccine. **Use of the items in this packet as instructed below is mandatory. Do NOT alter the materials or replace them with alternative documents.**

- **Provide items 1, 2 (including VIS supplements A-E), 3, and 4** to potential vaccinees as early as possible **before they make an appointment for vaccination**. Potential vaccinees should be given adequate time to obtain HIV or pregnancy testing, discuss contraindications with household contacts, talk to their health care providers, and check medical records.

- **Provide items 1-6 (including VIS supplements A-E)** to persons **when they present to the clinic** to receive smallpox vaccination. Give all individuals an opportunity to read the materials and view the "Decision Point" video (**item 7**) **before they consent to be vaccinated**. Offer to read the documents for individuals, especially if you suspect that they have difficulty understanding the material due to reading ability or language barriers. **Questions and concerns should be elicited from potential vaccinees and addressed by a trained health care provider.**

- Use the Patient Medical History and Consent Form (**item 8**) to confirm the absence of contraindications. Obtain signed consent and date on this form from all vaccinees. This document **must be retained by the clinic** for 5 years or the length of time required by state law, whichever is longer.

- Following immunization, provide vaccinees the Post-Vaccination and Follow-Up Sheet (**item 9**). Clinic sites should insert local or state telephone numbers for adverse event reporting.

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- Provide vaccinees a record of immunization following vaccination site examinations. It is the responsibility of each state to determine what type of permanent record of immunization they will use. Adult immunization cards may be obtained from the Immunization Action Coalition at www.immunize.org.

Providing the materials in this packet does not preclude clinic personnel from verbally educating potential vaccinees. Provide all individuals considering vaccination the opportunity to discuss the topics covered in these materials with a trained health care provider.